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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Gregor Reid

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04/08/2009

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EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,444	Applicant(s) REID ET AL.	
	Examiner MARIA LEAVITT	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7,9-11,13,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7,9-11,13,17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1633

Detailed Action

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Applicant's amendment filed on 12-31-2008 has been entered.
3. Status of claims. Claims 1, 2, 4, 5, 7, 9-11, 13, 17 and 18 are currently pending. Claims 6, 12, 14, 15, 19 and 20 have been cancelled by Applicants' amendment filed on 12-31-2008.
4. It is noted that allowability of claims 1, 2, 4, 5, 9-11 and 13 as stated in the previous office action of 11-12-2008 has been reconsidered in light of the guidance provided in the specification and knowledge available to one of ordinary skill in the art at the time of filing the present application and further in view of reconsideration of search under different premises. Accordingly, claims 1, 2, 4, 5, 9-11 and 13 are not allowable.
5. Therefore, claims 1, 2, 4, 5, 7, 9-11, 13, 17 and 18 are currently under examination to which the following grounds of rejection are applicable.

Response to Applicant's Remarks

Withdrawn objections/rejections in response to Applicants' arguments or amendments.

Claim Rejections - 35 USC § 112- First paragraph- Scope of Enablement

In view of applicants' cancellation of claims 14 and 19, rejection of claims 14 and 19 under 35 U.S.C. 112, first paragraph, is rendered moot.

Claim Rejections - 35 USC § 102

In view of applicants' cancellation of claim 15, rejection of claim 15 under 35 U.S.C. 102(b) as being anticipated by Falsen et al., Journal of Systematic Bacteriology, 1999, 217-221, is rendered moot.

Claim Rejections - 35 USC § 112- First paragraph- New Matter

In view of applicants' cancellation of claim 20, rejection of claim 15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is rendered moot.

Claim Rejections - 35 USC § 112- Second Paragraph

In view of applicants' amendment of claims 17 and 18 1 to recite " the method of claim 7", rejection claims 17 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite in that they fail to point out what is included or excluded by the claim language, has been withdrawn.

Claim Rejections - 35 USC § 103

In view of applicants' cancellation of claim 15, rejection of claim 15 and dependent claims 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Falsen et al., Journal of Systematic Bacteriology, 1999, 217-221, in view of BBL, Columbia Agar, Difco (of record) and Cavaliere (US Patent 6,277,370) and further in view of Gibson et al., (Gastroenterology, 1995, pp. 975-892), is rendered moot.

Objections maintained in response to Applicants' arguments or amendments.

Claims objection

Claims 1, 2, 4, 5, 7, 9-11, 13, 17 and 18 remain objected to because of the following informality. The capitalization of the term "claims", which is not preceded by a period is grammatically incorrect.

New grounds of rejection

Claim Rejections - 35 USC § 103

The specification as-filed defines a “pharmaceutically-acceptable carrier” as any one or more compatible solid or liquid able of being commingled without substantially decreasing the pharmaceutical efficacy of the composition (p. 11). Moreover, the specification as filed defines a prebiotic as “a prebiotic also includes a nutrient utilized by lactobacilli or bifidobacteria to stimulate and/or enhance growth of lactobacilli or bifidobacteria relative to pathogenic bacteria.” (p. 5, paragraph 1).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1633

Claims 1, 2, 4, 5, 7, 9-11 and 13 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Chrisope et al., (US Patent 6,468,526, Date of filing Dec 21, 2001) as evidenced by Macfarlane et al (1999, BMJ pp. 999-1003) in view of Hans et al., (US Patent 7,220,418; Date of PCT Publication Jan. 11, 2001) and further in view of Falsen et al., (1999, Journal of Systematic Bacteriology, pp. 217-221, of record)

Chrisope discloses a method for treating and preventing vaginal infections comprising administering to a female vaginal, rectal and oral medicants having a substantially pure culture of preserved microbial cells of *Lactobacillus* (col. 2, lines 50-56; col. 5, lines 20-25; 40-56). It is noted that the term probiotic was well known in the art at the time the invention was made to define commercial preparations of lactobacilli as evidenced by Macfarlane. Additionally, Chrisope teaches preferred *Lactobacillus* commonly present in the vagina including *Lactobacillus acidophilus*, *Lactobacillus jensenii* and *Lactobacillus crispatus* (col. 3, lines 46-54; col. 7, lines 33-40; col. 9, lines 32-35) (**Current claim 1, 2, 9, in part**). These strains are isolated from the vagina of a human (col. 9, lines 36-37) (**Current claim 13**). Moreover, Chrisope discloses that patients are administered *L. crispatus* CTV-05 capsules twice daily for three days (col. 30, lines 37-40). Alternatively, treatments include clindamycin cream followed by *L. crispatus* CTV-05 capsules (col. 31, lines 27-35), clearly indicating treatment of vaginosis with a first and a second probiotic (**Current claims 4, 5, 10, 11, in part**). Chrisope describes that the *Lactobacillus* is administered with a biologically active binding agent comprising a carbohydrate and a proteinaceous material that maintains genetically active cells for a period of at least 12 months *in vitro* (col. 8, lines 20-29), reading on the administration of a probiotic, e.g., *Lactobacillus* with a prebiotic (**Current claim 7**). Moreover, Chrisope teaches that *Lactobacilli*

Art Unit: 1633

are gram positive rods that are a part of the microbial flora of the human gut, mouth, and vagina (col. 1, lines 50-55).

Chrisope does not specifically teach non-pathogenic *Lactobacillus iners*.

However, at the time the invention was made, non-pathogenic *Lactobacillus* species were well known in the art as evidenced by the disclosure of Hans et al., including *Lactobacillus rhamnosus*, *Lactobacillus salivarius*, *Lactobacillus rhamnosus iners* and others (col. 2, lines 49-66 bridging to col. 3, lines 1-52). Indeed, Falsen et al., (International Journal of Systematic Bacteriology, 1999, 217-221) teaches the use of *Lactobacillus* as probiotics (i.e., dietary adjuncts for man and animal). Moreover, Falsen et al., teaches the discovery of a new species of the genus *Lactobacillus*: *Lactobacillus iners*, isolated from human specimens, vaginal discharge, endometrial cervical and others that were all gram positive (p. 218, col. 2) (**Current claim 5**).

Accordingly, in view of the benefits of using the numerous species of the genus *Lactobacillus* in a method for establishing a healthy virginal flora by administration of a therapeutically effective amount of a specific strain of *Lactobacillus* as taught by Chrisope, it would have been *prima facie* obvious for one of ordinary skill in the art, at the time the invention was made, to use the newly isolated species of *Lactobacillus iners*, particularly because Hans et al., and Falsen et al., teach that *Lactobacilli* are used as probiotics and the new isolated *Lactobacillus iners* is present in the microbial flora of the healthy vagina. So if administration of a therapeutically effective amount of non-pathogenic *Lactobacillus acidophilus*, *Lactobacillus jensenii* and *Lactobacillus crispatus* promotes a healthy vaginal, administration of a therapeutically effective amount of a *Lactobacillus iners* should be reasonably expected to promote a healthy bacterial flora for the same reason *Lactobacillus acidophilus*, *Lactobacillus*

Art Unit: 1633

jensenii and *Lactobacillus crispatus* treat and prevent vaginal infections – they are non pathogenic *Lactobacillus* species found in a healthy vagina.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chrisope et al., (US Patent 6,468,526, Date of filing Dec 21, 2001) in view of Hans et al., (US Patent 7,220,418; Date of PCT Publication Jan. 11, 2001) and Falsen et al., Journal of Systematic Bacteriology, 1999, 217-221, of record) as applied to claims 1, 2, 4, 5, 7, 9-11 and 13 above, and further in view of Macfarlane et al (1999, BMJ pp. 999-1003)

The disclosure of Chrisope, Hans and Falsen are outlined in the paragraphs above. The combined disclosure fails to teach inulin and fructo-oligosaccharides

However, at the time the invention was made, Macfarlane teaches that, to be effective, prebiotics should escape digestion in the upper gut, reach the large bowel, and be utilized selectively by restricted group of micro-organisms that have clear identified, health-promoting properties inducing inulin and their derivatives, the fructo-oligosaccharides (page 188, col. 2, paragraph 4) (**Current claims 17 and 18**).

Therefore, in view of the benefits of using inulin and fructo-oligosaccharides as prebiotics as taught by Macfarlane, it would have been *prima facie* obvious for one of ordinary skill in the art to modify the prebiotic administered in conjunction with a first or a second probiotic as taught by Chrisope, Hans and Falsen to include as a prebiotic inulin or fructo-oligosaccharides, particularly because inulin or fructo-oligosaccharides are well-known as preferential prebiotics in the prior art of record. There would have been a reasonable expectation of success to use inulin or fructo-oligosaccharides as taught by Macfarlane in the methods of

Art Unit: 1633

Chrisope, Hans and Falsen comprising administering to a female a substantially pure culture of preserved microbial cells of Lactobacillus orally or vaginal to generate a healthy virginal bacterial flora in females given the results of Chrisope, Hans, Falsen and Macfarlane demonstrating the success of the methodology and materials detailed in each of the disclosures.

Conclusion

Claims 1, 2, 4, 5, 7, 9-11, 13, 17 and 18 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

Art Unit: 1633

enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, PhD

Examiner, Art Unit 1633